

## **MOUTH SORE RELIEF PROFESSIONAL STRENGTH- benzocaine liquid**

**CVS Pharmacy**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Drug Facts**

#### **Active ingredient**

Benzocaine 20.0% (w/w) ..... Oral anesthetic/analgesic

#### **Use**

for the temporary relief of pain due to canker sores, minor irritation of the mouth and gums caused by dentures or orthodontic appliances, or minor injury of the mouth or gums

For oral use only

Allergy alert: do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

When using this product • do not use for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain or redness persists or worsens; or if swelling, rash or fever develops, see your doctor or dentist promptly. Do not exceed recommended dosage.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

• to assure formation of long-lasting film coating, dry affected area and apply medication undiluted with applicator • allow a few seconds for coating to form

#### **Other Information**

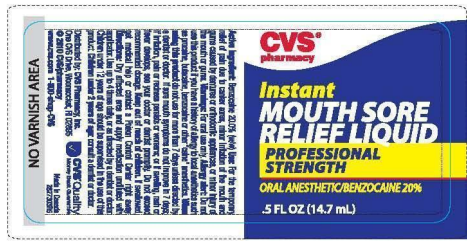
- do not use if package has been opened
- store at 20-25°C (68-77°F)
- close cap tightly after use to avoid evaporation
- avoid contact with eyes
- avoid contact with clothing and household/furniture surfaces to prevent possible staining
- this is a personal care item, and should be used by one individual only

#### **Inactive ingredients**

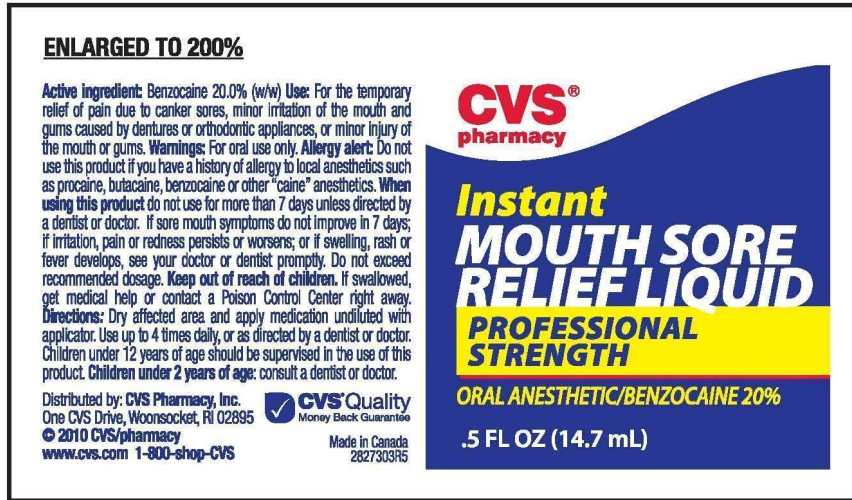
Benzyl Alcohol, Cetylpyridinium Chloride, Compound Benzoin Tincture, Dimethyl Isosorbide, Ethylcellulose, Flavor, Octylacrylamide/acrylates/butylaminoethyl/methacrylate Copolymer, Oleth-10, PEG-6, Propylene Glycol, Ricinus Communis (Castor) Seed Oil, SD Alcohol 38B, Sucralose, Tannic Acid.



- Limit of text/graphics to die line (1/16")
- Bleed allowance (1/8")
- Die Line



← Web Direction →



Design Label Systems Inc.

Label Name: CVS Pharmacy - 0.5 Fl oz Mouth Sore & Oral Relief

LBL Project # (TBA)

10th November, 2010 (Revised)

Dimensions - 1.5625" x 3.3125"

Print areas (as above)

Bleed area (as above)

Type area (as above)

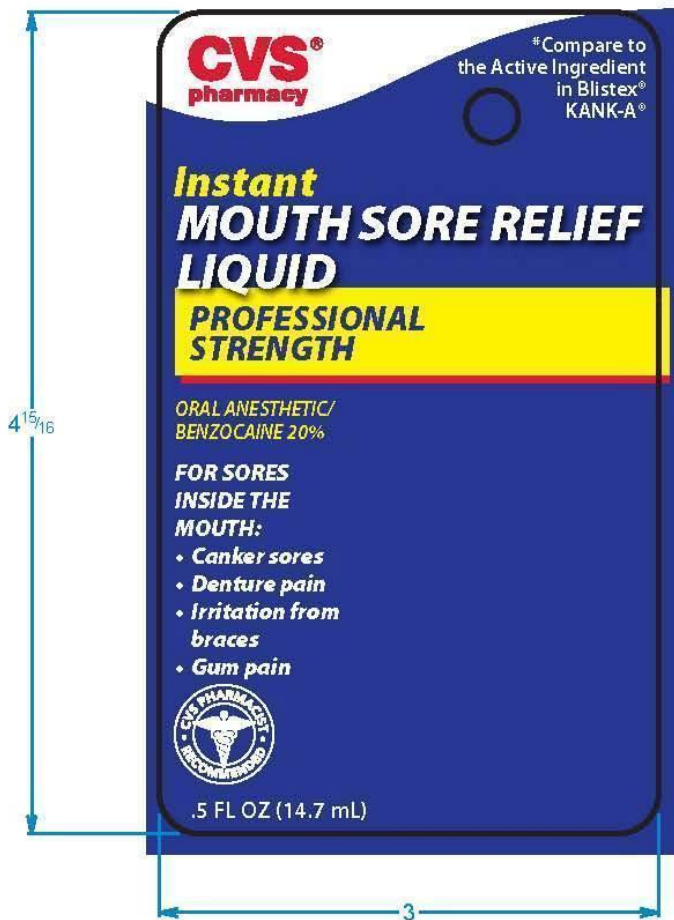
Preferred UPC orientation - (as above)

Print/Feed Direction based on above (Letter "M") - #3 or #4 (see chart at right)

LORNAMEAD, INC.		PROJECT INFO   PRODUCTION NOTES	
DATE:	NOVEMBER 17, 2010	PMS 2735C	<input type="text"/>
PROJECT:	CVS INSTANT MOUTH PAIN LIQUID LABEL	PMS 186C	<input type="text"/>
ITEM #:	2827303R5	YELLOW	<input type="text"/>
DIELINE#:	N/A		
SIZE:	3.3125" X 1.5625"		
FILE NAME:	CVS_PAIN_LIQ_LABEL_2827303R5.EPS		
PRINTER:	DESIGN LABEL SYSTEMS		
NOTES:	R5 - added "Made in Canada"; New dieline		
		<b>APPROVALS</b>	
		CREATIVE _____	
		MARKETING _____	
		R&D _____	
		QUALITY _____	
		PURCHASING _____	
		CFO _____	



Lornamead  
 Blister Card Kanka  
 D8669  
 SBS.020 Blister  
 May 19/09



LORNAMEAD, INC.		PROJECT INFO   PRODUCTION NOTES	
DATE: NOVEMBER 5, 2010	PMS 2735C	APPROVALS:	
PROJECT: CVS INSTANT MOUTH PAIN LIQUID CARD		CREATIVE:	
ITEM #: 2824303R4	PMS 186C		
<b>PER J. GRIFFITHS, VENDOR ALREADY HAD R4 ON FILE FROM CHANGES THAT THEY MADE. PRINTER CHANGED THIS TO R5 TO AVOID DUPLICATE. PROOF SENT ON 12/6/10.</b>			
PRINTER: ELLIS		PURCHASING:	
NOTES: R4 - Added "MADE IN CANADA"; Removed FSA logo		CEO:	

STAMFORD OFFICE | 5 HIGH RIDGE PARK | STAMFORD, CONNECTICUT 06905 | 203.517.1100  
 TONAWANDA OFFICE | 175 COOPER AVENUE | TONAWANDA, NEW YORK 14150 | 716.874.7190

• use up to 4 times daily, or as directed by a dentist or doctor • children under 12 years of age should be supervised in

the use of this product • children under 2 years of age: consult a dentist or doctor

## MOUTH SORE RELIEF PROFESSIONAL STRENGTH

benzocaine liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-830
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
MENTHOL (UNII: L7T10EIP3A)	4.34 mg in 1 g
ALCOHOL (UNII: 3K9958V90M)	280.87 mg in 1 g
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	0.1 mg in 1 g
TANNIC ACID (UNII: 28F9E0DJY6)	30 mg in 1 g
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	0.5 mg in 1 g
SUCRALOSE (UNII: 96K6UQ3ZD4)	3 mg in 1 g
BENZYL ALCOHOL (UNII: LKG8494WBH)	1 mg in 1 g
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	50 mg in 1 g
OLETH-10 (UNII: JD797EF70J)	5 mg in 1 g
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	5 mg in 1 g
RICINUS COMMUNIS SEED (UNII: 7EK4SFN1TX)	2 mg in 1 g
WATER (UNII: 059QF0K00R)	14.78 mg in 1 g
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	338.5 mg in 1 g
BENZOIN (UNII: L7J6A1NE81)	10 mg in 1 g

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (Mint Flavor #25797)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-830-38	1 in 1 BLISTER PACK		
1	NDC:59779-830-31	14.7 g in 1 BOTTLE, WITH APPLICATOR		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	10/01/2009	

**Labeler** - CVS Pharmacy (062312574)

**Registrant** - Lornamead (126440440)

**Establishment**

Name	Address	ID/FEI	Business Operations
CSR Cosmetic Solutions		243501959	manufacture(59779-830) , pack(59779-830)

Revised: 4/2011

CVS Pharmacy